MINUTES OF MEETING OF
HEALTH STRATEGIES COUNCIL
Department of Community Health, Division of Health Planning
Bainbridge College, 2500 E. Shotwell Street (Hwy.84),
Continuing Education Building / Room 416, Bainbridge, GA 31717-3249
Friday, May 21, 2004
■
11:00 am – 2:00 pm

Daniel W. Rahn, M.D., Chair, Presiding

MEMBERS PRESENT

William G. "Buck" Baker Jr., M.D.
Honorable Glenda M. Battle, RN, BSN
Harve R. Bauguess
David Bedell, DVM
Elizabeth Brock
Tary Brown
W. Clay Campbell
Nelson B. Conger, MD
Katie B. Foster
Charlene M. Hanson, Ed.D.,FNP
Felix Maher, DMD
Catherine Slade
Oscar S. Spivey, MD
Tracy M. Strickland
Kurt M. Stuenkel, FACHE (via conference call)

MEMBERS ABSENT

Edward J. Bonn, CHE
Anthony J. Braswell
Sonia Kuniansky
Reverend Ike E. Mack
Julia L. Mikell, MD
James G. Peak
Raymer Martin Sale, Jr.
Toby D. Sidman
Honorable Evelyn Turner-Pugh
Katherine L. Wetherbee
David M. Williams, MD

GUESTS PRESENT

Thomas Aversano, Johns Hopkins Medical Center
Bates Bailey, MD, Hamilton Medical Center
Armando Basarrate, Parker Hudson Rainer & Dobbs
Sammie L. Battle, Bainbridge, Georgia
Jeffrey Baxter, Nelson Mullins Riley & Scarborough
Dan Beall, The Strategy House
Charlotte Bedell, Tift County Commissioner
Taffey Bisbee, Gill/Balsano Consulting
Bill Calhoun, Langley & Lee
Lee Callier, West Georgia Medical Ctr.
Robert Copeland, MD, West Georgia Medical Ctr.

STAFF PRESENT

Neal Childers, General Counsel
Charemon Grant, Deputy General Counsel
Richard Greene, Esq.
Robert Rozier, Esq.
Rhathelia Stroud, Esq.
Stephanie Taylor

GUESTS PRESENT (CONTINUED)

Joy Davis, Rockdale Medical Center
Davis Dunbar, Piedmont Medical Center
Brian E. Daughdrill, Phears & Moldovan
Max Gilch, Eli Lilly
Alex Herbfeld, MD, John Archbold Memorial Hospital
Doug Holbrook, St. Joseph's Hospital of Atlanta
Doug Hurt, Tift Regional Medical Center
Stan Jones, Nelson Mullins Riley & Scarborough
Charlie Mikell, Court of Appeals of Georgia
Scott Rees, Powell Goldstein Frazier & Murphy
Charles Rehberg, Albany Surgical, PC
Ken Rhudy, Grady General Hospital
Bill Richardson, Tift Regional Medical Center
Kevin Rowley, St. Francis Hospital
Kevin Sass, Columbus Regional Hospital
Temple Sellers, Georgia Hospital Association
Thomas Shepherd, Gwinnett Hospital System
James L. Slary, Jr., MD, John Archbold Memorial Hospital
Charles T. Stafford, MD, Decatur County resident
LaDon Toale, Brooks County Hospital
Robert Trimm, Satilla Regional Medical Center

WELCOME AND CALL TO ORDER

The Council meeting was convened at 11:15 am. Richard Greene noted that the delay of the meeting was due to a setback in Dr. Rahn's travel plans. To facilitate the meeting, Elizabeth Brock, Vice-Chair welcomed members and guests to the Council meeting. She indicated that in the interest of time and in anticipation of Dr. Rahn's arrival that she would seek the approval of the minutes for the Standing Committees and the February Council meeting. This approach would allow Dr. Rahn, upon his arrival, to delve into the core parts of the agenda and to continue to preside over the meeting.

REVIEW AND APPROVAL OF MINUTES

Ms. Brock called on each of the chairpersons of the three standing committees to approve the minutes of their respective committee meetings. Clay Campbell made a motion, seconded by Elizabeth Brock to approve the minutes of the January 13, 2004 meeting of the Long Term Care (LTC) Standing Committee. All LTC committee members approved this motion. Dr. Spivey made a motion, seconded by Glenda Battle to approve the January 30, 2004 minutes of the Acute Care Standing Committee (ACSC). All ACSC members approved this motion. In the absence of the committee chair, Dr. David Williams, Cathy Slade made a motion, seconded by Dr. Baker to approve the minutes of the Special & Other Services Committee (SOSC). All SOSC members approved this motion. A motion to accept the minutes of the February 27, 2004 Council meeting was made by Dr. Bedell, seconded by Charlene Hanson. The Council unanimously approved this motion.

PRESENTATION OF ANGIOPLASTY RESEARCH PROJECT POTENTIALLY INCLUDING SELECTED GEORGIA HOSPITALS

Dr. Rahn indicated that he would defer the Chairman's Report until a future meeting in order to allow Dr. Thomas Aversano an adequate amount of time in which to make his presentation to the Council. He indicated that Dr. Aversano would discuss the Atlantic Cardiovascular Patient Outcomes Research Trial (CPORT study) which was a small research project, in a carefully controlled setting, that examined the ability of selected hospitals to perform primary angioplasty without open-heart surgical backup services.

Dr. Rahn said that Georgia's Specialized Cardiovascular Services TAC under Elizabeth Brock's leadership was convened during 2002, specifically to address the issue of the provision of angioplasty in hospitals without open-heart surgical backup services. The TAC recommended that no changes be made to the state's Specialized Cardiovascular Services CON rules but recommended that the state continue to examine changes at the national level and to consider other emerging trends in the industry. He said that the TAC encouraged providers to participate in research studies that would lead to advancing knowledge and information about any changes in the scope of practice in this specialized area. Dr. Rahn indicated that Mr. Greene contacted Dr. Aversano, on behalf of the Council, to obtain information about the next steps in the process that providers would need to undertake in order to participate in his upcoming research project unofficially called ("CPORT II").

Mr. Greene introduced Dr. Aversano to the Council. He thanked him for agreeing to speak to the Council and for participating in some of the Council's pre-meeting activities. In his introduction, Mr. Greene indicated that Dr. Aversano currently serves as the Associate Professor of Medicine at Johns Hopkins University School of Medicine and is the principal investigator of the CPORT research study. He said that Dr. Aversano would be addressing two key areas in his presentation namely, "CPORT I" research study -- its outcomes and findings and a new study, "unofficially CPORT II" research study. Upon a review of "CPORT II" research study he would then discuss some of the criteria for participation in "CPORT II" and would consider whether Georgia hospitals would be appropriate to participate in this

new study. Mr. Greene indicated that one of the needs of the "CPORT II" research project is to have an adequate base of participants from various demographic regions of the country. Mr. Greene indicated that given the high rates of cardiovascular diseases in the Southeastern United States, the participation of hospitals from the State of Georgia, in this type of research, would be beneficial.

Dr. Aversano started his presentation to the Council by distinguishing between the two forms of angioplasty, namely primary and elective. He said that primary angioplasty is undertaken in the setting of acute myocardial infarction. The specific form of acute myocardial infarction that is associated with a certain look on the ECG (ST segment elevation). It is called primary because there is no antecedent therapy. There has been no thrombolytic therapy. He indicated that primary angioplasty refers to a small population of patients. These were the patients that participated in "CPORT I". Elective angioplasty, on the other hand, is a misnomer. It is any angioplasty that is not ST segment elevation. This is a larger portion of the population.

Dr. Aversano provided the following handout materials to the Council. (See Appendix A)

- Summary of Requirements for Primary PCI Programs: Hospitals With and Without On-Site Cardiac Surgery
- Primary Percutaneous Coronary Intervention in Hospitals without On-Site Cardiac Surgery (chart)
  (Mr. Greene indicated that the State of Maryland's used this language as part of a "waiver program" to allow hospitals to participate in the "CPORT I" study). He indicated that this information was provided as a sample of how other states are accommodating this research study. He further said that waivers are not allowed in the State of Georgia).

Dr. Aversano's presentation to the Council was conducted via a slide presentation. The following statements represent some of the highlights of his presentation.

- There is a great deal of information for primary angioplasty. The information is very sound. Primary angioplasty is better than thrombolytic therapy for treatment of acute myocardial infarction for second heart-attacks or strokes;
- In the CPORT experience, the outcomes for hospitals without on-sight cardiac surgery are just as good and just as safe as those, under certain circumstances, in tertiary institutions.
- We are beginning to understand about the safety and efficacy of elective angioplasty performed in hospitals without onsite cardiac surgery, however the data are poor. There is a need for a definitive prospective trial.
- CPORT program has a formal development program
  - The primary angioplasty development program is meant to increment the staff level of expertise to include care of the primary angioplasty patient. No development program can substitute for experience.
  - Development of primary PTCA requires setting of standards, training of staff, particularly nursing and technical staff, development of logistics to ensure prompt and appropriate triage of patients with AMI and implementation of an ongoing quality management strategy.Conclusions of CPORT study of hospitals without on-site cardiac surgery that participated in a formal primary PCI development program and whose outcomes are monitored),
  - Primary angioplasty is superior to thrombolytic therapy for treatment of acute ST-segment elevation myocardial infarction
  - The benefit of primary angioplasty is evident in females and the elderly
  - Superiority is durable to 6 months after index myocardial infarction
  - Primary PCI is associated with reduced length of stay (LOS) and reduced rates of transfer

Dr. Aversano provided the institution, operator and patient inclusion criteria for participation in CPORT Registryl
The Institution inclusion criteria:

- Diagnostic cath lab
- Minimum 36 primary PCI's per year
- No onsite cardiac surgery or PCI program
- Primary PCI development program

The Operator inclusion criteria

- Must meet AHA/ACC competency criteria
- Must meet local credentialing criteria

The Patient inclusion criteria

- The patient must be thrombolytic-eligible
- The patient should be excluded from receiving shock therapy
- The patient must be able to give informed consent

CPORT REGISTRY (SUMMARY)

In hospitals without onsite cardiac surgery and without elective PCI program who participate in a primary PCI development program and whose outcomes are monitored

- Primary PCI is associated with low morbidity and mortality
- Primary PCI outcomes are significantly better than historical outcomes for thrombolytic therapy
- Primary PCI outcomes are at least as good as those from published primary angioplasty registries

CPORT (CONCLUSIONS)

- Under the conditions of CPORT registry that includes a primary PCI program development and outcomes monitoring, primary PCI is a safe and effective treatment for acute STEMI
- Extension of primary PCI to hospitals without on-site cardiac surgery is <u>one</u> possible way of expanding access to this better form of therapy for acute STEMI
- Departments of Health can use CPORT registry outcomes data to assist in the development and implementation of health care policy that maximizes access to the best form of therapy for the greatest number of patients

- No strong science to support performance of non-primary PCI at hospitals without on-site cardiac surgery
- A preliminary report issued by the American College of Cardiology and National Cardiovascular Data Registry (ACC/NCDR) which addressed the issue of clinical outcomes in coronary angioplasty centers with off site versus on site cardiac surgery capabilities recommended that participation in ACC-NCDR should be mandated for PCI programs with off-site backup surgery to assure that this strategy is fairly assessed, compared, and monitored on a national level

ATLANTIC CPORT- NON-PRIMARY PCI STUDY

The motivation behind this project is:

Need for research
Data suggest equivalent safety and efficacy
Patient/family/physician convenience-continuity of care
Sustain primary PCI program
Increased safety
Regionalization model may not be ideal
Cost reduction

Current proposal includes the following:

- Non primary PCI study
- Multi-center, multi-state randomized trial
- Potential State Involvement

Dr. Aversano's presentation is attached to the minutes as Appendix B.

DR. AVERSANO RESPONDED TO THE FOLLOWING QUESTIONS POSED BY COUNCIL MEMBERS AND STAFF

Richard Greene: How much lead-time would be required to participate in this new study (for a hospital with an existing cardiac cath lab, providing that the hospital meets all of the CPORT and state criteria)?
Dr. Aversano: This process would likely take a minimum of 3-4 months.

Elizabeth Brock: Where does the American College of Cardiology (ACC) stand on "CPORT II"?
Dr. Aversano: There is no formal position from the ACC. They (ACC) have made the exact decision that the State of Georgia has made. Do not change the guidelines for non-primary angioplasties until there is greater evidence. Preliminary evidence suggests safety but quality evidence suggests that some additional research is necessary. Evidence suggests, under certain conditions, monitoring and development programs can be done at hospitals without surgical backup.

Dr. Rahn: Are there other trials of this nature underway in this country?
Dr. Aversano: Not that I am aware of.

Elizabeth Brock: Have other states signed on to participate in "CPORT II"?
Dr. Aversano: The states of Maryland and New Jersey have expressed an interest. New York is in a TAC subcommittee meeting process and may participate in a demonstration project. Ohio and Alabama also are considering participation.

Elizabeth Brock: What is it going to cost each state to participate in "CPORT II"?
Dr. Aversano: Participating institutions pay for the development and data collection process of the project in their institution. The person charged with data collection will be trained by our office. The data is sent to my office for analysis. The state also would need to be able to access the information, excluding (personal) patient identification information.

Elizabeth Brock: There is a nursing shortage in the State of Georgia, who will train the staff?
Dr. Aversano: My staff would train the staff. It is a very labor-intensive undertaking. There is a requirement to have affiliations with tertiary institutions. Also, if there are staff in the cardiac cath lab that are not experienced in intervention, there is a requirement that the nursing staff go to a tertiary institution for a minimum amount of observation and training.

Cathy Slade: Does the information that you have presented represent minimum requirement?
Dr. Aversano: Usually, there is a minimum CPORT requirement. It is customary that each state would add a set of additional requirements in order for hospitals to participate in the study. The hospital would write a letter to the state expressing an interest in participation in the study.

Charlene Hanson: How did you derive at the minimum number of procedures that should be performed annually?
Dr. Aversano: These clinical criteria were established by the American College of Cardiology (ACC).

Council member: Why are angioplasties so expensive?
Dr. Aversano: The cost of such a program varies however this area requires a specialized staff and patients usually enter through the emergency room for interventional procedures. Much of the capital costs are equipment costs.

Elizabeth Brock: Does there need to be an access problem in the area before such a program can be initiated?
Dr. Aversano: No. However it is of critical importance to have transfer agreements and adequate transportation systems in place, particularly in rural areas.

Dr. Rahn noted that some of the questions posed by council members identify the need to adequately assess both individual (provider) competencies and system competencies prior to the initiation of such a research project. Mr. Campbell agreed with this summation and further said that not all health systems or providers are appropriate for participation in this type of research project.

Rhathelia Stroud inquired as to what the next steps in the process would be. Dr. Rahn said that the Council has endorsed the recommendation of the Specialized Cardiovascular TAC, not to make any changes to the existing rules but to explore opportunities to participate in the acquisition of knowledge and to participate in ongoing research. The CPORT registry for primary angioplasty is ongoing and the State of Georgia is being presented with the potential to participate in a randomized control study, still under development for non-primary angioplasty. Dr. Rahn recommended that Council members request that the Department go forward with developing draft rules to determine how participation could occur.

Following the question and answer period, Clay Campbell, made a motion, seconded by Charlene Hanson, to authorize staff to develop a draft set of rules for insertion into the state's existing rules that would allow selected hospitals to participate in the registry phase of "CPORT I" and to allow participation in "CPORT II", which involves the provision of elective and non-primary cardiovascular intervention.

Tary Brown asked about the involvement of the Specialized Cardiovascular TAC in the development of any draft rules. Elizabeth Brock said that she would encourage the inclusion of the TAC in the development of any draft rules. She emphasized that members of the TAC are associated and involved with the ACC and indicated that they be involved in the development of any proposed language. She said that following the TAC's review, the proposed language should be brought back to the Council. She said that recent decisions by the TAC and the Council were made in regards to participation in the registry phase of "CPORT I" (primary angioplasty). She said that no references were made to participation in "CPORT II" during the TAC's deliberations. Ms. Brock read an excerpt from the minutes of the February 27th, 2004 Council meeting:

> *Dr. Mikell made the recommendation that all hospitals that are approved to participate in the CPORT study should be allowed to do so. This motion was seconded by Kurt Stuenkel and was unanimously passed by the Council.*
>
> *Robert Rozier suggested that the Council's recommendation should be more specific and should read as follows: " The Council agrees that some specific language should be inserted in the Specialized Cardiovascular Services rules to allow those hospitals that meet the CPORT guidelines to participate in the pilot program, under the study guidelines". The Council unanimously accepted this amended language to its earlier recommendation*.

She reiterated that when this discussion occurred, it referred specifically to "CPORT I" not CPORT II. She asked whether the Council should arbitrarily allow hospitals to participate in this new program or whether the TAC should be involved.

Cathy Slade encouraged the continued involvement of the TAC. She recommended that the Specialized Cardiovascular TAC be reconvened so that they could work with staff to develop any draft rules for participation in "CPORT II". Several members indicated that they were unaware of earlier Council discussions regarding hospital participation in "CPORT II" research project

Mr. Stuenkel indicated that he recalls a discussion about "CPORT II" at the February 27, 2004 Council meeting. He said that the term "emergent" was used. He read the following excerpt from the minutes of the February 27, 2004 Council meeting:

> *Kurt Stuenkel made a motion, seconded by Dr. Bedell to reconvene the Specialized Cardiovascular Services TAC to examine the merits of allowing hospitals to perform emergent and primary angioplasty without open-heart backup. Dr. Rahn inquired as to whether there was a need to reconvene the TAC since they had already encouraged hospitals seeking to provide angioplasty without open-heart surgical backup to consider participation in the CPORT study. Council members agreed that since the TAC had already encouraged hospitals to participate in the CPORT pilot study, that there is no need to reconvene the Specialized Cardiovascular Services TAC at this time. Following substantial discussion, the motion to reconvene the Specialized Cardiovascular Services TAC failed (by unanimous vote) to achieve support from the Council".*

Richard Greene indicated that "CPORT II" was discussed at the last Council meeting. He indicated that "CPORT II" is not the correct name of the study and referred members to the following excerpt from the February 27, 2004 minutes:

> *Mr. Stuenkel indicated that the committee had considerable discussion about this area. He said that while the Specialized Cardiovascular Services TAC indicated that they would not recommend that the committee be reconvened unless or until the American College of Cardiology (ACC) has made any changes to their rules, that he has received information which indicates that several states are allowing hospitals to provide both emergent and primary angioplasty without open-heart surgical backup.*

Following considerable discussion, Mr. Greene indicated that one approach could be the development of two sets of rules; one which provides language for participation in "CPORT I" (primary angioplasty) and another set of rules for participation in "CPORT II", both primary and elective angioplasties. He said that Department staff would not develop any draft rules in a vacuum.

Glenda Battle asked whether the state's cardiovascular services rules should not be changed subsequent to hospital participation in the CPORT study since Dr. Aversano would have already accepted the hospitals for participation in the pilot project. Council members were reminded that the state's specialized cardiovascular services rules would have to be changed prior to any hospital's participation in the CPORT research project.

Ms. Brock indicated that this is an extremely important discussion. She said that she feels that the TAC should be reconvened and allowed to provide guidance about hospital participation in the "CPORT II" research study.

Dr. Rahn asked for clarification on the process. He indicated that he does not want to introduce a 3-6 month delay for decision-making. He asked if it would be necessary to bring back any draft language to the Council from the TAC or whether the Dept. could develop rules for participation in the "CPORT II" study. Ms. Brock indicated that the TAC should assist the staff in the development of any rules.

Mr. Childers indicated that his recollection of the last meeting is that the TAC should not be reconvened.

Clay Campbell reiterated his motion: to authorize staff to develop a draft set of rules for insertion into the state's existing rules that would allow selected hospitals to participate in the registry phase of "CPORT I" and to allow participation in "CPORT II", which involves the provision of elective and non-primary cardiovascular intervention.

Dr. Rahn indicated that if the Council would like the TAC to be reconvened then a substitute motion would have to be introduced. Following review of Mr. Campbell's motion, Dr. Rahn asked the Council to vote. He indicated that a vote against Mr. Campbell's motion would be a vote to reconvene the TAC for the purpose of providing guidance to the state about participation in the "CPORT II" research study. A vote in favor of the motion would direct the staff to develop draft rules to allow participation in the registry phase of "CPORT I" study (primary angioplasty) and the randomized control trial ("CPORT II") for non-primary angioplasty. Those voting in support of the motion (8); those voting in opposition to the motion (6); Those abstaining from vote (2). The motion passed.

Dr. Rahn recommended that the Department advise the members of the Specialized Cardiovascular Services TAC of the decisions that were made at today's meeting and further recommended that the Department seek clinical expertise from members of the Specialized Cardiovascular Services TAC in the development of any draft language for participation in the "CPORT I & II" studies.

Following additional Council discussion in this area, Dr. Rahn emphasized that this draft language would be brought back to the Council for approval and adoption. Elizabeth Brock expressed concern about the lack of clinical expertise within the Department to draft this proposed language. She recommended that several members of the Specialized Cardiovascular Services TAC, including Dr. Wenger, be consulted in the development of any proposed rules. Mr. Greene said that the Department also would seek input from a wide range of sources.

Dr. Rahn thanked Dr. Aversano, on behalf of the Council, for visiting the State of Georgia and for a most informative presentation.

PRESENTATION OF DRAFT PROPOSED HEALTH PLANNING RULES FOR COUNCIL REVIEW, COMMENTS AND RECOMMENDATIONS

Dr. Rahn introduced Robert Rozier, attorney, Office of General Counsel to review the draft rules. He indicated that the draft rules were sent to all members of the Council prior to the meeting. Mr. Rozier indicated that these draft rules should not be considered "proposed" until they have been approved by the DCH Board and issued for public comment. This would initiate the formal rule adoption process.

Mr. Rozier said that the Department has attempted to streamline and standardize the CON process. In addition, he said that some technical modifications have been made to the rules, including renumbering and clarification. He said that much of the proposed changes attempt to provide guidance and to clarify how the Department currently interprets administrative rules.

Mr. Rozier initiated the review of the proposed changes however given the quantity of changes and time constraints the Council did not have an opportunity to review all of the proposed changes. Dr. Rahn acknowledged that several Council members have expressed concerns about some areas of the draft proposed rules. He read a letter to the Council which he received from the Medical Association of Georgia. The letter expressed concerns about several of the proposed changes. Elizabeth Brock recommended that a series of public hearings be held around the state to seek input prior to the presentation of the rules to the Board of Community Health. Neal Childers suggested that the Council consider the review of the proposed changes at a time prior to the next regularly scheduled meeting in August.

Dr. Rahn encouraged Council members to read the proposed rules. The Council voted unanimously to continue the review of the proposed draft rules via conference call at a time prior to the August Council meeting. Robert Rozier agreed to continue to facilitate the Council discussion and reminded Council members that a public hearing would be held on the proposed rules following issuance by the DCH Board. A summary document of the recommended changes to the draft proposed rules appear as Appendix C.

ACCEPTANCE OF PUBLIC COMMENTS

Dr. Rahn asked if anyone present wanted to provide any public comments on the draft proposed rules. Noone indicated the desire to speak.

OTHER BUSINESS

Ms. Taylor indicated that information pertaining to the Council's conference call meeting will be placed on the Department's website or sent out electronically. There being no further business, the meeting adjourned at 2:20 pm. The next regularly scheduled Council meeting is planned for Friday, August 27th at 11:00 am.

Minutes taken on behalf of Chair by Stephanie Taylor.

Respectfully Submitted,

Daniel Rahn, MD, Chair

Note: Subsequent to the May meeting, Department staff identified an error on the map entitled: "Existing and Approved Adult Cardiac Catheterization and Open Heart Surgery Facilities (as of May 2004)". The map was revised to correct the inaccurate placement of an open-heart surgical services program in Ware County. The map should have indicated that there are two open-heart surgical services program in Bibb County. The correction on the map has been made and appears as Appendix D.

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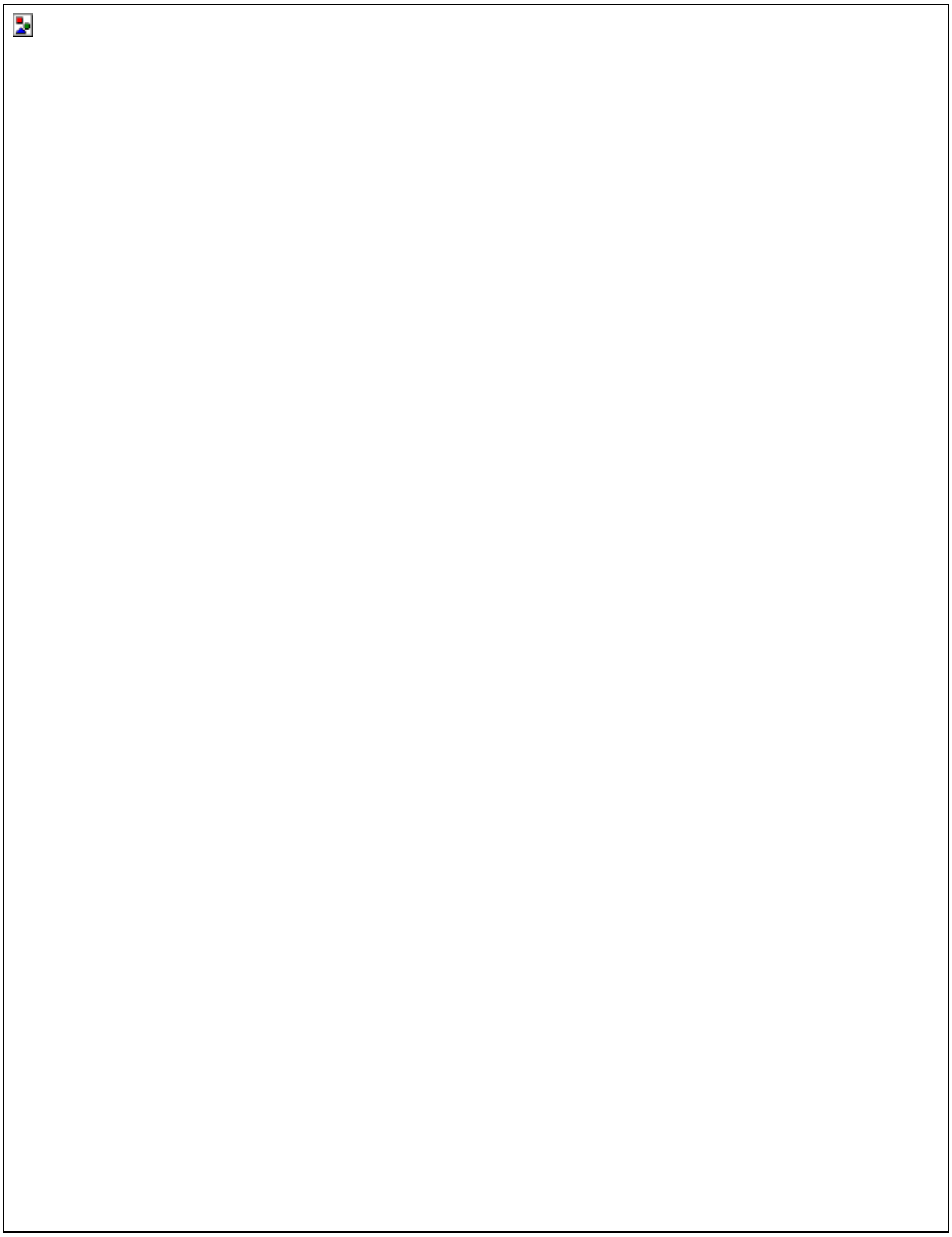
APPENDIX A

DOCUMENTS PROVIDED BY THOMAS AVERSANO, MD TO COUNCIL MEMBERS
(Language inserted into the Specialized Cardiovascular Services CON rules used by the State of Maryland to allow eligible hospitals to participate in the CPORT research study)

- Summary of Requirements for Primary PCI Programs: Hospitals With and Without On-Site Cardiac Surgery
- Primary Percutaneous Coronary Intervention in Hospitals without On-Site Cardiac Surgery. (Note: Please contact the Division of Health Planning to obtain a copy of this document).



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APPENDIX B

Slide Presentation to the Health Strategies Council

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Delivered by Thomas Aversano MD
Associate Professor of Medicine
Johns Hopkins University School of Medicine
& The Johns Hopkins Health System

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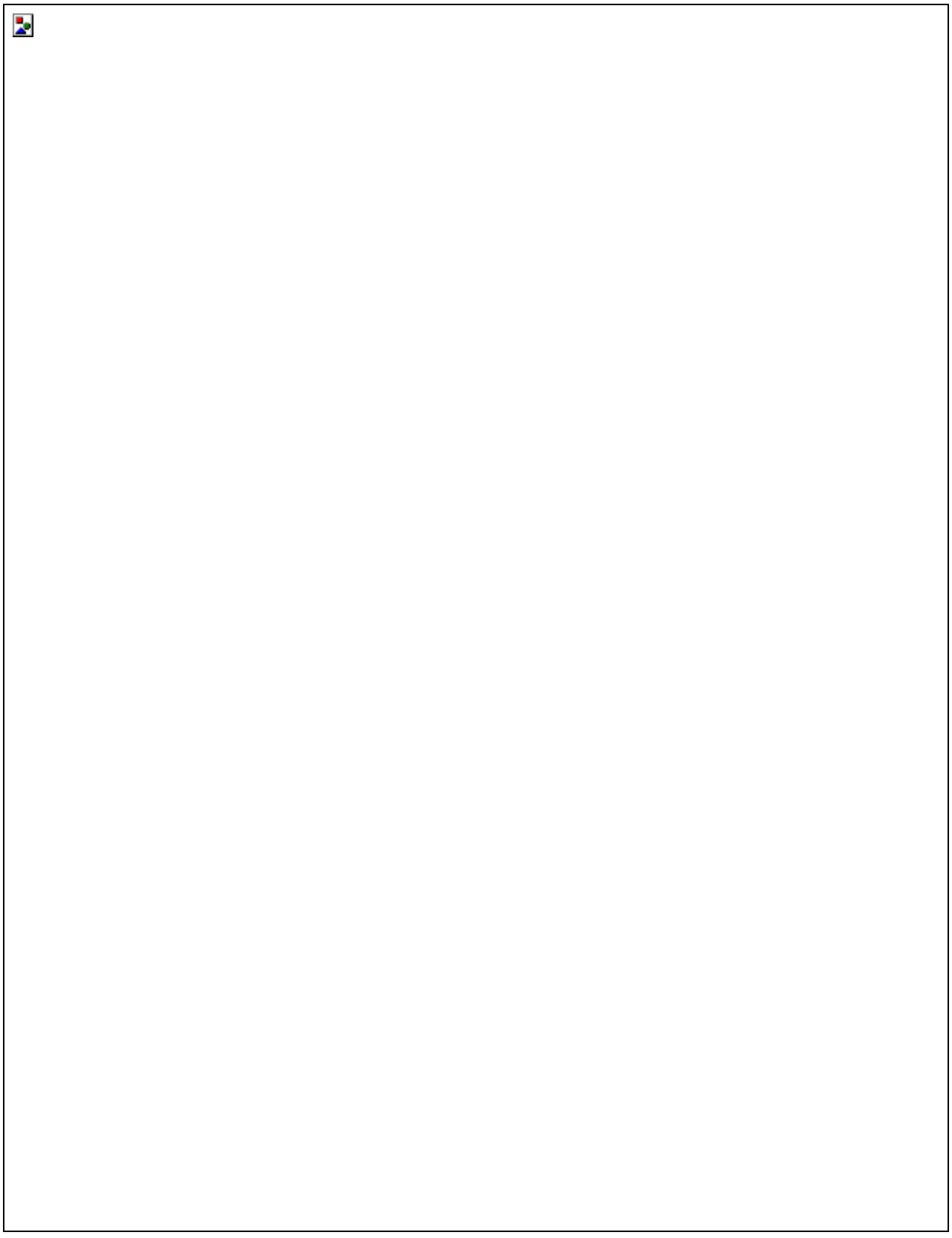
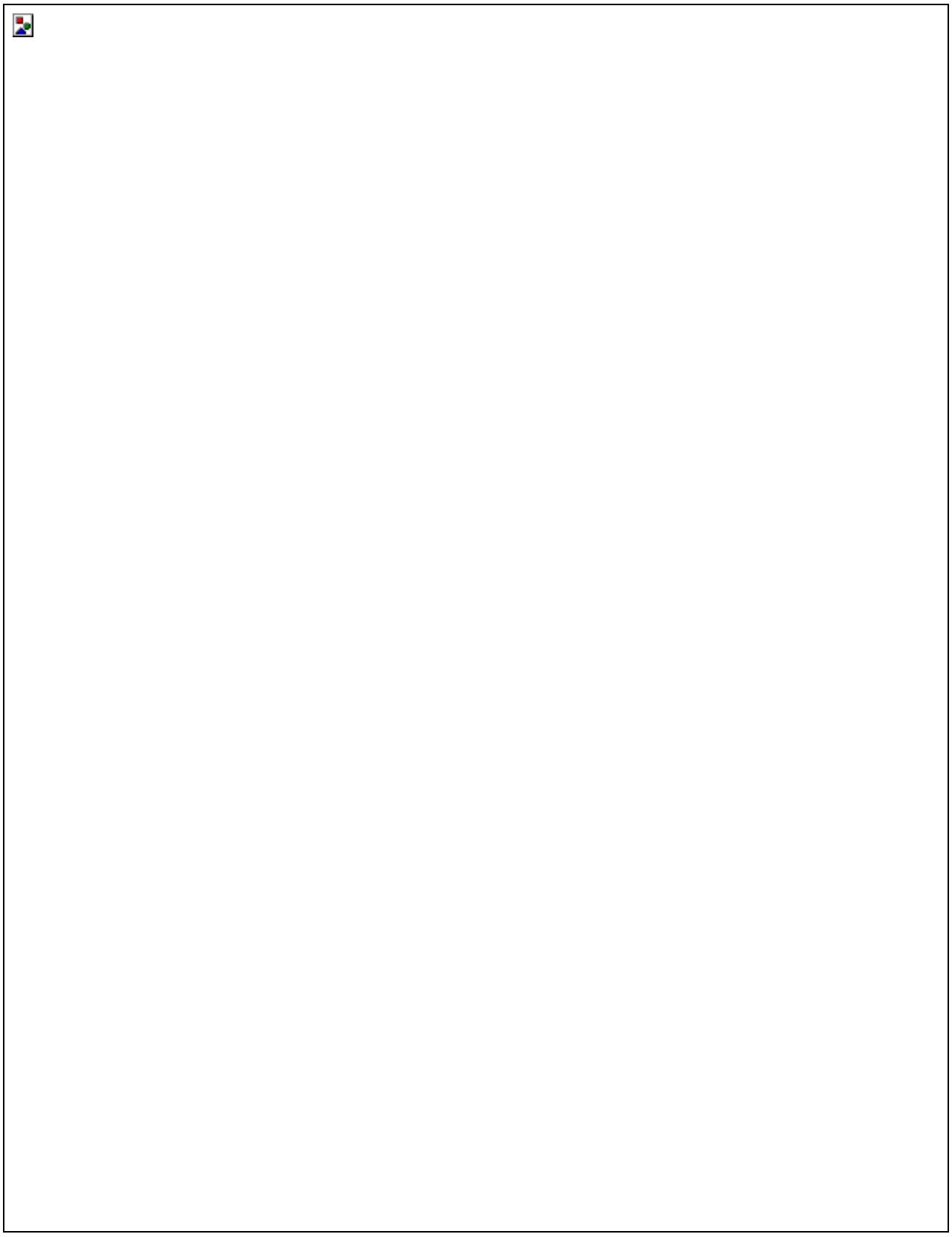
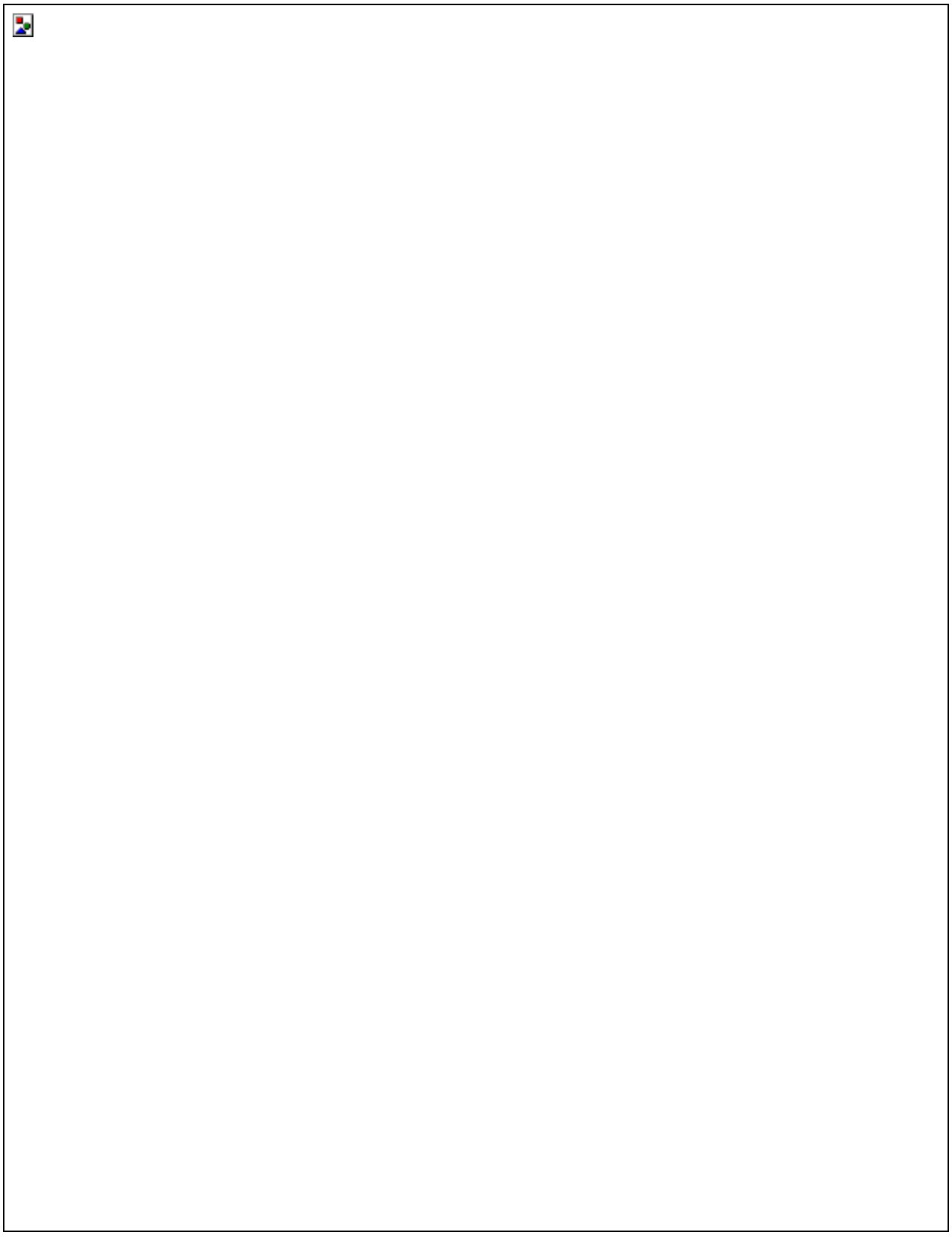
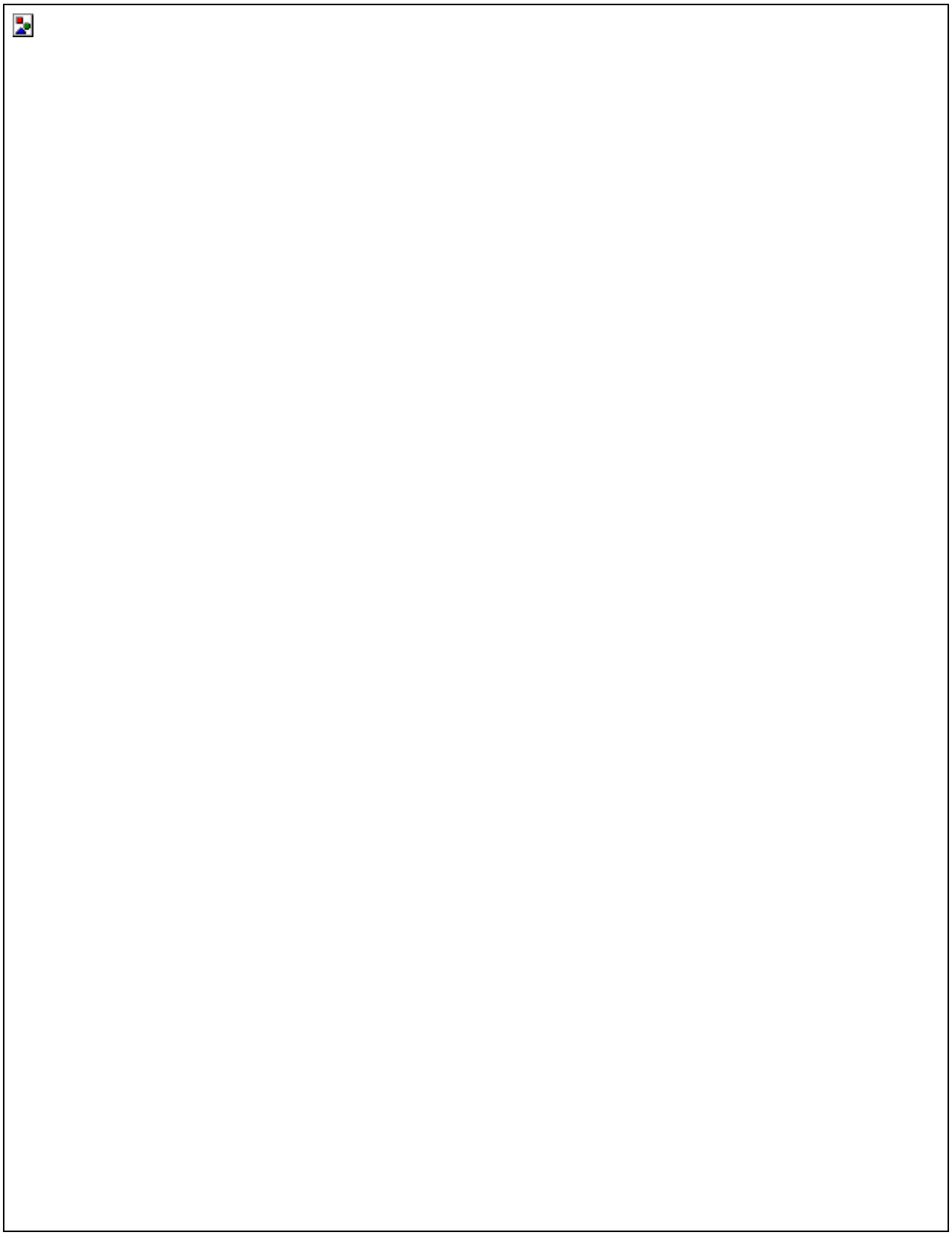
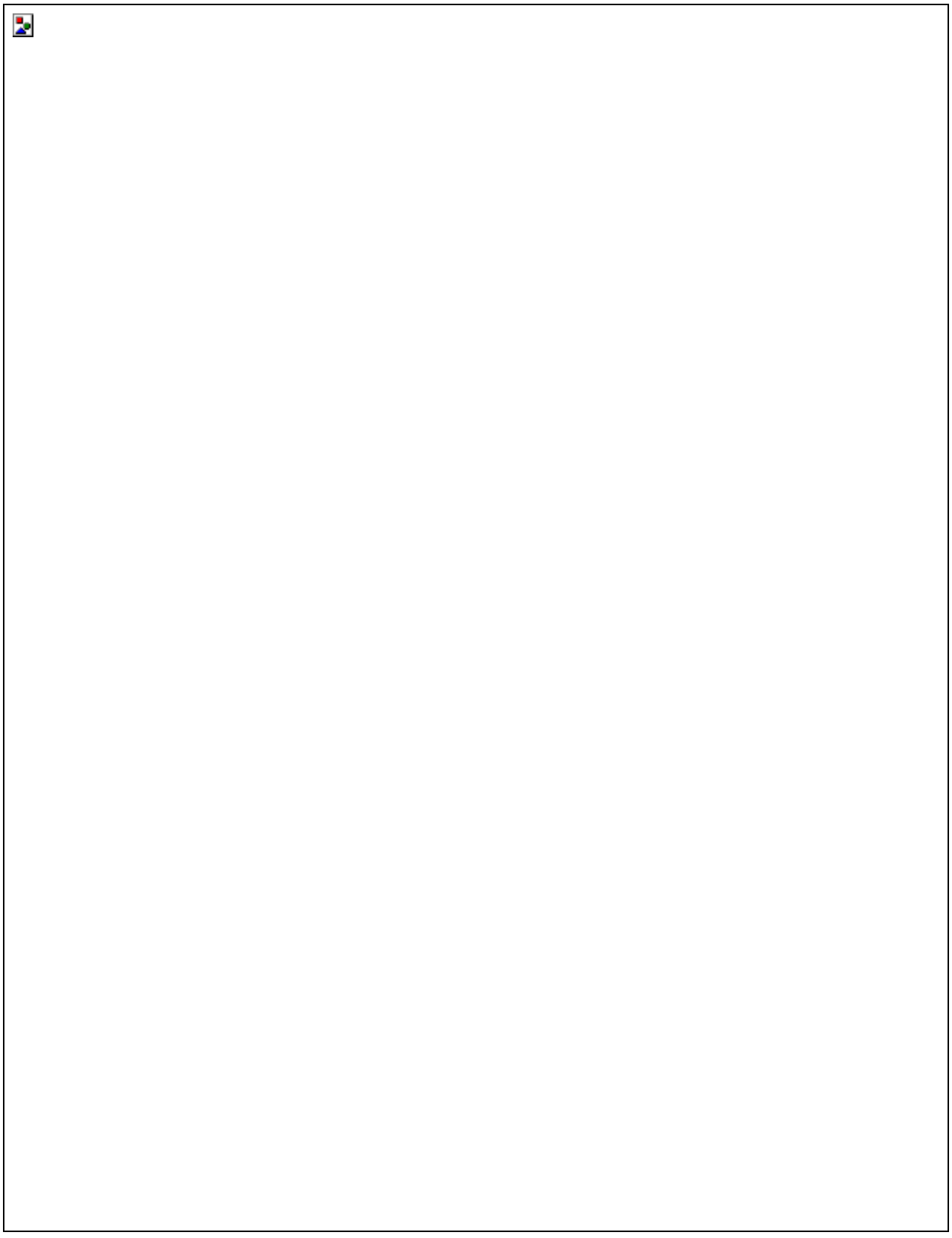
Bainbridge, Georgia
May 21, 2004

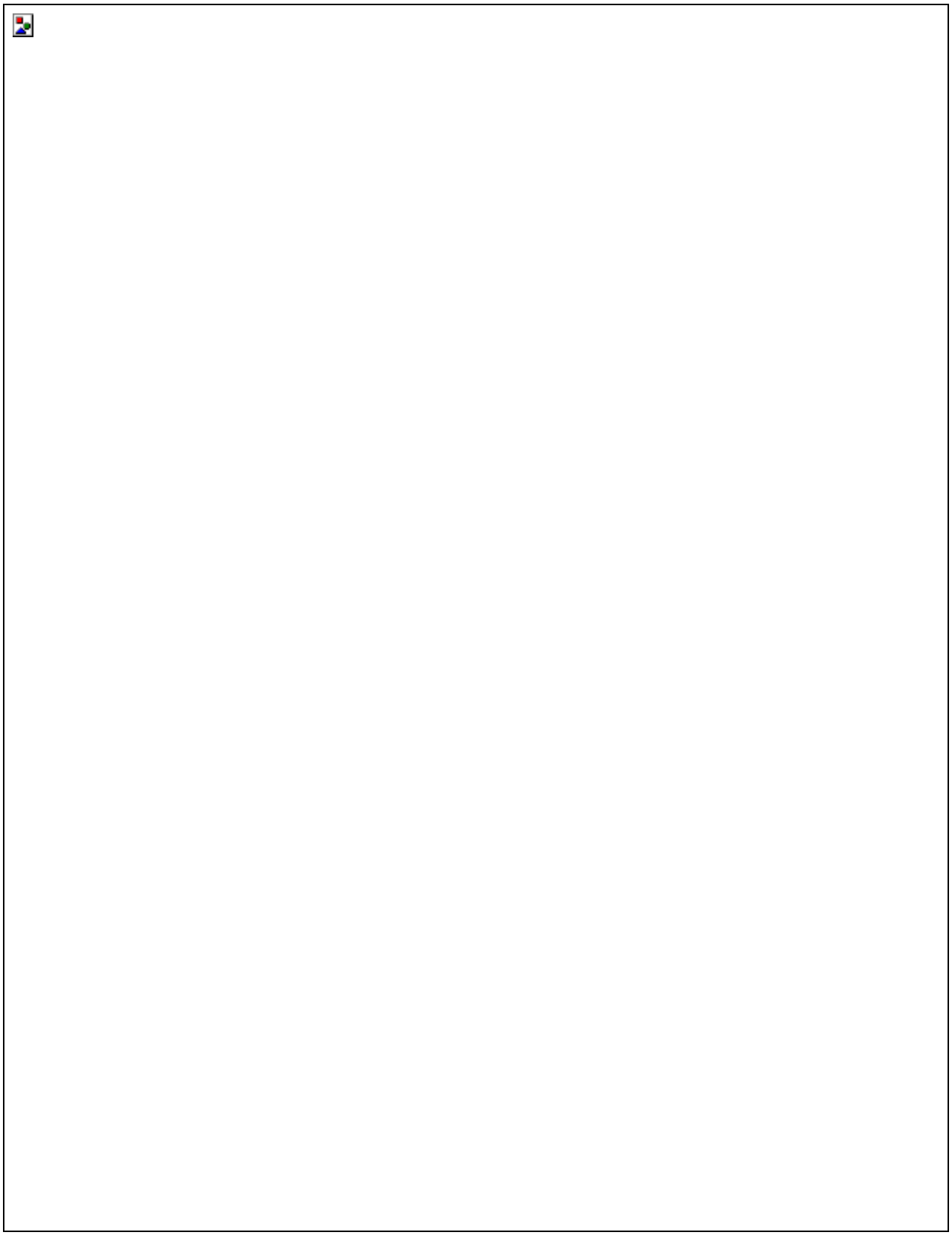












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APPENDIX C

EXPLANATION OF SUBSTANTIVE MODIFICATIONS
TO THE
DRAFT PROPOSED HEALTH PLANNING RULES

	Explanation of Substantive Modifications	**Rule No.**	**Page No.**
1	Former Rule 272-1-.02 is proposed to be repealed as the section repeats verbatim the statutory provision related to the Health Strategies Council. It is the Department's intent to streamline the Rules by removing language that only repeats exactly what the Health Planning Statute provides.	Repealed 272-1-.02	11
2	The Department proposes to add several definitions and clarify several terms to reflect the Department's interpretation of the Rules. The purpose is to ensure that the public is given adequate notice of the Department's interpretation and application of the Rules. Significantly, the Department has proposed the following additions: • The terms "bad debt," "charity care" and "indigent care" have been defined to provide clarity to health care facilities and to ensure that the Department's application of indigent and charity care commitments is adequately defined and consistently applied. • The terms "associated with and simultaneously developed or proposed," "by or on behalf of," "capital expenditure" and "threshold" have been added or amended to ensure that the public is aware of the expenditures that should be included in calculating the expenditure thresholds of the Statute. These terms simply clarify the Department's interpretation of these issues.	111-2-2-.01 111-2-2-.01(9) 111-2-2-.01(14) 111-2-2-.01(29) 111-2-2-.01(8) 111-2-2-.01(11) 111-2-2-.01(12) 111-2-2-.01(43)	31 33 34 37 33 33 34 42
3	The effective period or duration of Certificates of Need for projects involving construction is proposed to be amended. The Department proposes allowing applicants to propose phases and reasonable completion dates based on those phases. The 30-month period of the previous rule was often not enough time for substantial construction projects to be completed.	111-2-2-.02(5)	49
4	More detailed guidelines are proposed to be added to the requirements for requesting extensions of the effective period or duration of projects. The Department wishes to add clear guidelines to the circumstances that would justify an extension. The granting of unwarranted extensions affects need calculations and service to the healthcare population.	111-2-2-.02(7)	50

	Explanation of Substantive Modifications	Rule No.	Page No.
5	The Department proposes that approved CON projects that are not implemented in a full and complete fashion be considered to be modified to include only those items and services that are complete upon the Certificate's construction deadline. This ensures that services that are never implemented are removed from the official numerical inventory, and thus they become available to other entities that do wish to serve the need.	111-2-2-.02(9)	51
6	Guidelines are proposed to be added to the exemption for replacement of equipment. The Department wishes to ensure that all equipment that an entity claims is replacement equipment is comparable to the replaced equipment. This clarification gives the public and providers written standards to apply in regards to replacement equipment.	111-2-2-.03(1)(p)	59-60
7	The rules regarding requests for letters of determinations are proposed to be modified to ensure that adequate information is supplied in each request in order for the Department to make an appropriate and knowledgeable determination. Also, as the Department spends a great amount of effort and resources in responding to requests for letters of determination, a fee of $250.00 will be required for such requests.	111-2-2-.03(2)	62-63
8	The Department recommends substantial changes to the rules regarding the submittal of requests for a Letter of Non-Reviewability (LNR) for below threshold diagnostic or therapeutic equipment. The Department recommends a clarification that these rules are applicable to all requests regarding equipment below threshold not just MRI units. The Department also wishes to recommend a fee of $500.00 for such requests, as they require a great deal of resources. The other requirements that are proposed to this section only reflect the Department's continuing interpretation of the exemption for below threshold equipment. These requirements seek to standardize the way in which such requests are received to ensure that the Department makes consistent and knowledgeable determinations. The modifications also add a requirement to report final costs to the Department.	111-2-2-.03(3)	63-69

	Explanation of Substantive Modifications	Rule No.	Page No.
9	The Department suggests substantial changes to the rules regarding the submittal of requests for a Letter of Non-Reviewability (LNR) for physician-owned, single-specialty, office-based ambulatory surgery centers. The Department would like to require a fee of $500.00 for such requests as they require a great deal of resources. The other requirements that have been suggested to be added to this section only reflect the Department's continuing interpretation of the exemption for these types of ASCs. These requirements seek to standardize the way in which such requests are received to ensure that the Department makes consistent and knowledgeable determinations. In addition, a modification would require 100% physician ownership of these ASCs to more closely track the statutory provisions.	111-2-2-.03(4)	70-85
10	New requirements regarding challenging determinations of the Department have been suggested to ensure that the public is aware of the Department's current informal practices related to the receipt of challenges.	111-2-2-.03(6)	86
11	Requirements have been suggested regarding the submission of periodic reports to the Department to ensure that all entities receiving CONs provide post-approval reporting and project status updates. It is important for the Department to receive accurate status reports as the need for additional projects is affected by approved projects. This section simply codifies the Department's current practices of requiring project status updates.	111-2-2-.04(2)	91
12	The Department wishes to clarify certain instances that would lead to the revocation of a Certificate of Need.	111-2-2-.05(1)(f)	96
13	The Department suggests that the filing fee for CON applications be increased. Also, the Department wishes to add a requirement stating its current policy of requiring additional filing fees for modifications to projects that have increased total project costs.	111-2-2-.06(3)	102
14	The Department's current requirements for determining an application complete have been modified and clarified. For the most part, these modifications simply clarify the Department's current practices in this regard.	111-2-2-.06(4)	103-105
15	Requirements regarding the submittal of letters of opposition to projects under review have been proposed to be amended. The requirements suggest a definitive time frame for submittal of opposition to ensure that applicants have adequate time to respond to opposition and to ensure that the Department has adequate time to consider the issues raised in opposition.	111-2-2-.07(1)(f)	110-111

	Explanation of Substantive Modifications	Rule No.	Page No.
16	The Department wishes to obviate the distinction between additional information and amendment to ensure that all information is received by the Department in an adequate time frame for review.	111-2-2-.07(1)(h) 111-2-2-.08(1)	112 119,121
17	Requirements to review considerations are added to ensure that all applicants make some minimum commitment to provide indigent and charity care.	111-2-2-.09(1)(g)	133-134
18	The Department recommends a new to clarify issues surrounding the interaction of the service-specific review considerations and the general considerations. This new rule would lay out the re-organization of the service-specific rules. The service-specific rules would be re-organized to locate related rules together. For example. All acute care related rules are located in the .20 subsection. All long-term care related rules are located in the .30 subsection. All special and other health services are located in the .40 subsection. Additional Rules are recommended to ensure that service inventories and numerical need calculations are kept up to date and accurately reflect the need for health services within the State. These rules reflect the Department's current and continuing practices in regard to need calculations.	111-2-2-.10 111-2-2-.10(4)	140-141 141
19	In certain circumstances, the Department wishes to add a requirement in the home health rule to ensure that the unnecessary duplication of services is limited within a particular county. Currently applicants have the habit of splitting an individual home health county, which leads to 2 providers being approved in any county. This duplicates services and is not desirable.	111-2-2-.32(3)(b)3.	216
20	As a result of several Review Board hearings, the Department recommends the clarification of the Medicaid exception for home health need determinations.	111-2-2-.32(3)(c)2.	216
21	With the modification of the Rules related to the effective periods of projects encouraging applicants to submit the phased time periods for implementation, the duration exception for CCRCs will no longer be necessary, as a CCRC will be able to propose reasonable time periods for construction of phases under the general considerations.	111-2-2-.33(2)	220
22	The exemptions to the Comprehensive Inpatient Physical Rehabilitation rule are no longer applicable. They were only applicable at the time the rule was adopted in 1993 and 1994; therefore, the Department now proposes that they be removed.	111-2-2-.35	235-236

	Explanation of Substantive Modifications	Rule No.	Page No.
23	The Department recommends that the PET rule be modified to remove an exception for participants designated by the Georgia Cancer Coalition. The Georgia Cancer Coalition has not and does not designate individual participants.	111-2-2-.41(3)(c)	248
24	The Department recommends that the radiation therapy rule be modified to remove references to and exceptions based on participation in the Georgia Cancer Coalition. The Georgia Cancer Coalition has not and does not designate individual participants.	111-2-2-.42	254,255

MINUTES OF MEETING OF
HEALTH STRATEGIES COUNCIL
Department of Community Health, Division of Health Planning
Bainbridge College, 2500 E. Shotwell Street (Hwy.84),
Continuing Education Building / Room 416, Bainbridge, GA 30303
Friday, May 21, 2004

APPENDIX D

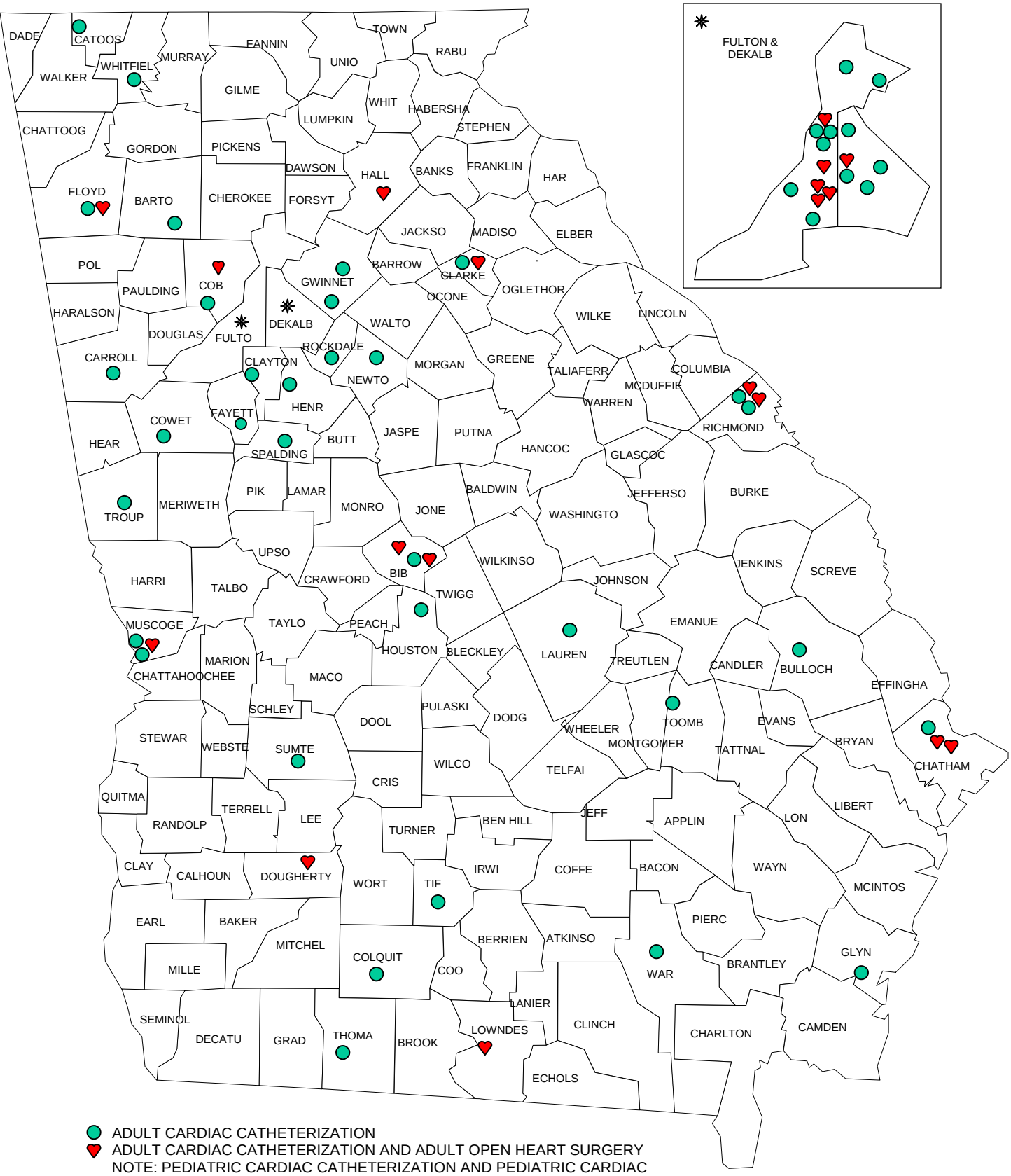
Existing and Approved Adult Cardiac Catheterization and Open Heart Surgery Facilities (as of May 2004)

This map was revised to correct the inaccurate placement of an open-heart surgical services program in Ware County. The map should have indicated that there are two open-heart surgical services program in Bibb County; none in Ware County. There is adult cardiac catheterization program in Ware County.

GEORGIA

Existing and Approved Adult Cardiac Catheterization and Open Heart Surgery Facilities

(as of May 2004)



ADULT CARDIAC CATHETERIZATION

ADULT CARDIAC CATHETERIZATION AND ADULT OPEN HEART SURGERY

NOTE: PEDIATRIC CARDIAC CATHETERIZATION AND PEDIATRIC CARDIAC SURGERY ARE PROVIDED IN DEKALB AND RICHMOND COUNTIES AND PEDIATRIC CARDIAC CATHETERIZATION IS PROVIDED IN CHATHAM COUNTY.